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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/018,200 | 01/23/2002 | Lakshmi Arehole Devi | 5986/1F684-US1 | 4935 |

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[REDACTED] EXAMINER

LANDSMAN, ROBERT S

[REDACTED] ART UNIT [REDACTED] PAPER NUMBER

1647

DATE MAILED: 04/25/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|----------------------|---------------------|--|
| Office Action Summary | Applicant No. | Applicant(s) | |
| | 10/018,200 | DEVI ET AL. | |
| | Examiner | Art Unit | |
| | Robert Landsman | 1647 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on _____.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-35 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) _____ is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) 1-35 are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 - a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____. | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Lack of Unity

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1 in part, 2, 6 in part, 9-12, 16, 19-23, drawn to a heterodimeric receptor wherein the first receptor is a delta opioid receptor and the second receptor is an opioid receptors, including kappa and mu.

Group II, claim(s) 1 in part, 3, 6 in part, 9-11, 13, 16, 19-23, drawn to a heterodimeric receptor wherein the first receptor is a delta opioid receptor and the second receptor is a dopamine receptor.

Group III, claim(s) 1 in part, 4, 6 in part, 9-11, 14, 16, 19-23, drawn to a heterodimeric receptor wherein the first receptor is a delta opioid receptor and the second receptor is an adrenergic receptor.

Group IV, claim(s) 1 in part, 5, 9-11, 15, 16, 19-23, drawn to a heterodimeric receptor wherein the first receptor is a delta receptor and the second receptor is a chemokine receptor.

Group V, claim(s) 1 in part, 2, 7 in part and 9-12, 17, 19-23, drawn to a heterodimeric receptor wherein the first receptor is a kappa opioid receptor and the second receptor is a delta opioid receptor.

Group VI, claim(s) 1 in part, 3, 7 in part, 9-11, 13, 17, 19-23, drawn to a heterodimeric receptor wherein the first receptor is a kappa opioid receptor and the second receptor is a dopamine receptor.

Group VII, claim(s) 1 in part, 4, 7 in part, 9-11, 14, 17, 19-23, drawn to a heterodimeric receptor wherein the first receptor is a kappa opioid receptor and the second receptor is an adrenergic receptor.

Group VIII, claim(s) 1 in part, 5, 7 in part, 9-11, 15, 17, 19-23, drawn to a heterodimeric receptor wherein the first receptor is a kappa opioid receptor and the second receptor is a chemokine receptor.

Group IX, claim(s) 1 in part, 2, 8 in part and 9-12, 18, 19-23, drawn to a heterodimeric receptor wherein the first receptor is a mu opioid receptor and the second receptor is a delta opioid receptor.

Group X, claim(s) 1 in part, 4, 8 in part, 9-11, 14, 18, 19-23, drawn to a heterodimeric receptor wherein the first receptor is a mu opioid receptor and the second receptor is an adrenergic receptor.

Group XI, claims 24-28, drawn to a bispecific compound.

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Group XII, claim 29 in part and 33 in part, drawn to a pharmaceutical composition comprising a delta opioid receptor ligand and a kappa or mu opioid receptor ligand and a method of treating disease.

Group XIII, claim 29 in part and 33 in part, drawn to a pharmaceutical composition comprising a delta opioid receptor ligand and a dopamine receptor ligand and a method of treating disease.

Group XIV, claim 29 in part and 33 in part, drawn to a pharmaceutical composition comprising a delta opioid receptor ligand and a adrenergic receptor ligand and a method of treating disease.

Group XV, claim 30 in part and 34 in part, drawn to a pharmaceutical composition comprising a kappa opioid receptor ligand and a delta opioid receptor ligand and a method of treating disease.

Group XVI, claim 30 in part and 34 in part, drawn to a pharmaceutical composition comprising a kappa opioid receptor ligand and a dopamine receptor ligand and a method of treating disease.

Group XVII, claim 30 in part and 34 in part, drawn to a pharmaceutical composition comprising a kappa opioid receptor ligand and an adrenergic receptor ligand and a method of treating disease.

Group XVIII, claim 30 in part and 34 in part, drawn to a pharmaceutical composition comprising a kappa opioid receptor ligand and a chemokine receptor ligand and a method of treating disease.

Group XIX, claim 31 in part and 35 in part, drawn to a pharmaceutical composition comprising a mu opioid receptor ligand and a delta opioid receptor ligand and a method of treating disease.

Group XX, claim 31 in part and 35 in part, drawn to a pharmaceutical composition comprising a mu opioid receptor ligand and an adrenergic receptor ligand and a method of treating disease.

Group XXI, drawn to a method of treating a disease using the compound of claim 24.

The invention listed as Groups I-XXI do not relate to a single inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical feature for the following reasons: the special technical feature of Groups I-X the independent and distinct heterodimeric receptors. The special technical feature of Group II is a bispecific ligand. The special technical feature of Groups XII-XXI is pharmaceutical compositions comprising ligands for each of the independent and distinct receptors as well as methods of treating disease. The special technical feature of each group is not the same, or does not correspond to the special technical feature of any other Group. The products of Groups I-XXI are structurally and functionally distinct. The Groups are not linked by a special technical feature within the meaning of PCT Rule 13.2 so as to form a single inventive concept.

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A telephone call was made to Irina Vainberg on April 22, 2003 to request an election to this restriction. However, no election was made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 CFR § 1.48(b) and by the fee required under 37 CFR § 1.17 (h).

Advisory information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Landsman whose telephone number is (703) 306-3407. The examiner can normally be reached on Monday - Friday from 8:00 AM to 5:00 PM (Eastern time) and alternate Fridays from 8:00 AM to 5:00 PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623.

Official papers filed by fax should be directed to (703) 308-4242. Fax draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Robert Landsman, Ph.D.
Patent Examiner
Group 1600
April 23, 2003



ROBERT LANDSMAN
PATENT EXAMINER